

REMARKS

This Amendment is submitted in response to the Office Action mailed on October 11, 2002. The Office Action rejects Claims 1, 15, and 26 under 35 U.S.C. § 112. In addition, the Office Action rejects Claims 1-4, 6-12, 15-23, and 26-34 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,200,950 ("*Mark*") in view of U.S. Patent No. 6,326,355 ("*Abbruzzese*"). Claim 5 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over *Mark* in view of U.S. Patent No. 6,355,612 ("*Balleve*"), or alternatively in view of U.S. Patent No. 5,278,288 ("*Kawasaki*") and U.S. Patent No. 5,968,586 ("*Etzel*"). In addition, Claims 13, 14, 24, 25, 35, and 36 are rejected under 35 U.S.C. § 103(a) as being unpatentable over *Mark* in view of *Abbruzzese*, and in further view of U.S. Patent No. 6,077,504 ("*Cavaliere*"). Applicants respectfully submit that in view of the Amendment that the rejections have either been overcome or are not proper for the following reasons.

Claims 1, 15, and 26 stand rejected under 35 U.S.C. § 112. The claims stand rejected due to the use of the word "macronutrients." Applicants submit that Claims 1, 15, and 26 have been amended to delete the word "macro" and substitute therefor "micro." For the foregoing reasons, Applicants submit that the 35 U.S.C. § 112 rejections have been overcome and should be withdrawn.

Claims 1-4, 6-12, 15-23, and 26-34 under 35 U.S.C. § 103(a) as being unpatentable over *Mark* in view of *Abbruzzese*. Applicants respectfully submit that this rejection is not proper.

The present invention is directed to methods for improving muscle protein synthesis, preventing muscle loss, and accelerating muscle recovery. The methods include the steps of administering a therapeutically effective amount of a composition including a protein source which provides at least 8% of the total calories of the composition and which includes at least 50% by weight, of the protein source, whey protein, a lipid source having an omega 3 to 6 fatty acid ratio of approximately 5:1 to about 10:1 and which provides at least 18% of the total calories of the composition, a carbohydrate source, and a micronutrient profile comprising at least vitamin E and vitamin C.

Mark relates to general nutritional compositions. As admitted by the Examiner, *Mark* does not disclose or suggest using a micronutrient profile comprising at least vitamin E and vitamin C or Applicants' claimed lipid percentage. See Office Action at 3. Moreover, this reference clearly does not disclose or suggest a method for improving muscle protein synthesis, a

method for preventing muscle loss, or a method for accelerating muscle recovery. In fact, *Mark* only states that the compositions are utilized to treat metabolically stressed patients, which are defined as "patients who, due to either a disorder or condition, are unable to tolerate whole protein diets and need fluid restriction, while at the same time cannot tolerate elevated protein levels or excess fluid." See col. 6, lines 13-20. There is no mention or suggestion whatsoever that the composition could be used for improving muscle protein synthesis, preventing muscle loss, or accelerating muscle recovery.

Abbruzzese does not remedy the deficiencies of *Mark*. For example, *Abbruzzese* relates to methods of inhibiting metabolic and cytokine associated features of cachexia. See col. 3, lines 11-15. Moreover, the compositions are primarily designed for use with patients suffering from various forms of cancer. See col 5, lines 6-12. There is no suggestion for using the composition in *Abbruzzese* in a method for improving muscle protein synthesis, preventing muscle loss, or accelerating muscle recovery. The composition disclosed in *Abbruzzese* is designed to inhibit signal transduction and cytokine activity. See col. 6, lines 20-25. Moreover, the use of antioxidants in *Abbruzzese* is intimately related to their use as cancer reducing agents, not for any properties related to muscle growth or maintenance. See col 7, lines 5-15. Therefore, even if the disclosure of *Abbruzzese* was combined with *Mark*, it would not render the claimed invention obvious since there simply is no mention or suggestion for using any of these composition in the manner set forth in the pending claims. Accordingly, Applicants respectfully submit that the rejection of the claims based on this combination of references has been overcome.

Claim 5 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over *Mark* in further view of *Balleve* or *Kawasaki* and *Etsel*. Applicants respectfully submit that the obviousness rejection is not proper for the following reasons.

First, Applicants note *Mark* fails to disclose or suggest the claimed invention for the reasons noted above. Moreover, *Balleve* or *Kawasaki* and *Etsel* do not remedy the deficiencies of *Mark*.

Balleve is completely silent as to methods for improving muscle protein synthesis, preventing muscle loss, or accelerating muscle recovery. Each of the claims of the present invention is limited to such a method. Moreover, *Balleve* does not disclose or suggest compositions having a micronutrient profile comprising at least vitamin E and vitamin C.

Therefore, even if one skilled in the art were to combine these reference it would not render Applicants' claimed invention obvious.

Kawasaki and *Etsel* also fail to remedy the deficiencies of *Mark*. Neither *Kawasaki* nor *Etsel* mentions or suggests methods for improving muscle synthesis or nutritional compositions having a micronutrient profile including at least vitamin E and vitamin C. Therefore, Applicants respectfully submit that Claim 5 is allowable and the obviousness rejections have been overcome.


Claims 13, 14, 24, 25, 35, and 36 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over *Mark* in view of *Abbruzzese*, and in further view of *Cavaliere*. As discussed in detail above, *Mark* in view of *Abbruzzese* fails to disclose or suggest the claimed invention. *Cavaliere* fails to remedy the deficiencies of both of these references. *Cavaliere* does not mention or suggest methods for improving muscle protein synthesis, preventing muscle loss, or accelerating muscle recovery. Furthermore, it should be noted that *Cavaliere* does not mention or suggest compositions having a micronutrient profile comprising at least vitamin E and vitamin C. Therefore, *Cavaliere* either alone or in combination with the cited references, does not disclose or suggest the claimed invention. Accordingly, Applicants respectfully submit that the obviousness rejection is not proper and therefore request withdrawal of same.

For the foregoing reasons, Applicants respectfully request reconsideration of their patent application and earnestly solicit an early allowance of same.

Attached hereto is a marked-up version of the changes made to the claims by the current amendment. The attached page is captioned "Version with Markings to Show Changes Made."

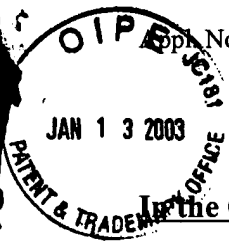
Respectfully submitted,

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

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In the Claims:

Claims 1, 15, and 26 have been amended as follows:

1. (Amended) A method for improving muscle protein synthesis comprising the steps of administering a therapeutically effective amount of a composition comprising: a protein source which provides at least 8% of the total calories of the composition and which includes at least 50% by weight, of the protein source, whey protein, a lipid source having an omega 3 to 6 fatty acid ratio of approximately 5:1 to about 10:1 and which provides at least 18% of the total calories of the composition, a carbohydrate source, and a ~~macronutrient~~ micronutrient profile comprising at least vitamin E and vitamin C.

15. (Amended) A method for preventing muscle loss in an individual at risk of same comprising the steps of administering a therapeutically effective amount of a composition comprising: a protein source which provides at least 8% of the total calories of the composition and which includes at least 50% by weight, of the protein source including whey protein, a lipid source having an omega 3 to 6 fatty acid ratio of approximately 5:1 to about 10:1 and which provides at least 18% of the total calories of the composition, a carbohydrate source, and a ~~macronutrient~~ micronutrient profile comprising at least vitamin E and vitamin C.

26. (Amended) A method for accelerating muscle mass recovery comprising the steps of administering a therapeutically effective amount of a composition to an individual comprising: a protein source which provides at least 8% of the total calories of the composition and which includes at least 50% by weight, of the protein source including whey protein, a lipid source having an omega 3 to 6 fatty acid ratio of approximately 5:1 to about 10:1 and which provides at least about 18% of the total calories of the composition, a carbohydrate source; and a ~~macronutrient~~ micronutrient profile comprising at least vitamin E and vitamin C.